QUESTION 1
There is overlap in the deliverables required by this RFP and the deliverables required by contracts awarded in response to earlier RFPs (e.g. RFP-05-04). Are costs associated with deliverables that are part of earlier awarded contracts to be included in the overall RFP-05-08 proposal costs? Or should such costs be identified in the RFP-05-08 technical proposal as covered by a separate contract and not included in the RFP-05-08 cost proposal?

ANSWER 1
Costs that support the technical elements of this RFP but are currently funded with other US Government contracts should be identified as such in the business proposal. Those costs should not be included in the final estimate.

QUESTION 2
The ability to produce 150 million doses within 6 months of declaration of pandemic in the proposed facility will depend on the actual yield of a future pandemic strain. As the yield of the future pandemic strain is unknown at the time of proposal submission and Offerors are not required to create contingency plans for a low yielding future pandemic strain, what should be the basis for projected pandemic vaccine strain yields? Can Offerors assume that facility design and capacity calculations can be based on yield data of seasonal influenza strains on Offeror's cell substrate?

ANSWER 2
The US Government will accept an averaged yield based on the performance of influenza strains manufactured as part of contracts administered under other BARDA contracts.

Yes, the offerors may assume that facility design and capacity calculations can be based on yield data of seasonal influenza strains on the Offeror's cell substrate.

QUESTION 3
Can DHHS clarify its position on indemnification if the pandemic vaccine requested to be made by DHHS under this RFP is not an already licensed vaccine? It is our understanding that current legislation limits the timeline for existing pandemic flu indemnification such that it may not be applicable to or available to the 8-year base contract period or the post award 17-year option period.

ANSWER 3
The Government has taken the foregoing comments under consideration and is weighing a number of options about how to best address contractor concerns in this area. A more definitive response to the question will be provided as part of any amended RFP.

QUESTION 4
It is assumed that Intellectual Properties related to reassortant technology can create restrictive covenants on the use of that I.P. in the scope of work outlined in DHHS's final RFP. If pandemic vaccine is required to be made for the USG using a reassortant strain seed virus provided by DHHS, there may be claims that royalties or other financial

compensation is due on the sale of product to the USG by offerors. Can DHHS clarify the status of the USG position on this issue and whether or not a formal waiver to this potentially restrictive criteria would be afforded by DHHS? Does DHHS have an agreement(s) in place that allows other parties to use this technology in conjunction with DHHS affiliated warm based manufacturing contracts or in the event of a pandemic?

ANSWER 4
The Government has taken the foregoing comments under consideration and is weighing a number of options about how to best address contractor concerns in this area. A more definitive response to the question will be provided as part of any amended RFP.

QUESTION 5
Does DHHS anticipate amending the referenced September 29th proposal submission date of the RFP to a later date to allow offerors to compile a proposal that better meets the requirements of DHHS?

ANSWER 5
No, proposal submission is due by 3:00PM on Monday, September 29, 2008.

QUESTION 6
It is anticipated that offerors will be able to produce enough bulk vaccine to meet the requested 150 M dose target in 6 months for pandemic vaccine and have capacity to formulate, fill and finish the vaccine. However, vials, needles and other supplies not manufactured by the offeror may be in short supply or not available due to national or global demand for such products. To what extent does DHHS anticipate having materials stockpiled to enable fill and finish of vaccine if such a shortage of non-offeror materials should occur?

ANSWER 6
Materials for finishing doses will be the subject of another RFP issued by BARDA.

QUESTION 7
Assuming that an offeror does not currently have funding from DHHS for all required clinical trials for licensure of a pandemic vaccine, will the clinical bridging studies to be funded by DHHS through this mechanism include conducting clinical trials required by FDA for licensure of a pandemic vaccine?

ANSWER 7
Clinical bridging studies will be funded; however, studies that are required by FDA/CBER to achieve licensure will not be funded.

QUESTION 8
Question #68 in the Q&A published on 14Aug addressed in part the mandatory criteria to have completed a Phase I clinical trial in using Offeror's mammalian cell-based influenza candidate by the time applications are submitted in response to this RFP. We would like to request additional clarity on this requirement.

Original Question #68: Also, how is HHS defining the 'successful completion of Phase I clinical trials' for the purposes of this solicitation?

HHS Response to Question #68 (14Aug): Per the RFP, successful completion of Phase I clinical trials will include safety and immunogenicity data for a mammalian, cell-based influenza vaccine candidate at the time of proposal submission. This data may be submitted as raw data in a draft report."

Follow-up Question: Is HHS willing to modify or remove the mandatory requirement for successful completion of Phase I clinical trials for a mammalian, cell-based influenza vaccine candidate as a prerequisite to proposal submission? For example, can egg based seasonal or pandemic influenza vaccine clinical data be submitted? Can seasonal mammalian, cell-based influenza vaccine clinical data be submitted?

ANSWER 8

No, the mandatory requirement for successful completion of Phase I clinical trials for a mammalian, cell-based influenza vaccine candidate as a prerequisite to proposal submission will not be removed.

No, egg based seasonal or pandemic influenza vaccine clinical data may not be submitted to satisfy the mandatory criteria.

However, clinical trial data for inter-pandemic or seasonal mammalian cell-based influenza vaccine candidates will satisfy this element of the mandatory criteria.

QUESTION 9

Question #11 in the Q&A published on 14Aug addressed the limitations on cost reimbursement for CLIN 0008. We would like to request additional clarity on this issue.

Original Question #11: In discussing CLIN 0008, the draft RFP states that “estimates shall be revised to reflect the actual cost to manufacture influenza vaccine product and adjuvant (if applicable) as determined in Milestone 6. The actual cost of each option shall not exceed the estimated cost plus fixed fee for each line item:” (p. 3). Please clarify what is meant by this -- is the draft RFP indicating that the “Total Estimated CPFF” shall not exceed this amount? Actual costs may be difficult to estimate - particularly considering the number of option years at issue; presumably CPFF for those option years will reflect actual costs plus the fixed fee amount. Please confirm.

HHS Response to Question #11 (14Aug): Yes, the total estimated cost plus fixed fee shall not exceed this amount. Please note, however, that costs will be reimbursed based on actual costs incurred in the performance of the work, but are subject to the “Limitation of Cost (FAR 52.232-20)” clause which will be incorporated into the awarded contract(s) by reference.

Follow-up Question: Will contractors be reimbursed for their actual costs plus a fixed fee subject to the limitation of costs, or will their cost recovery be limited to their estimated cost plus fixed fee (unless actual costs are less than estimated costs: then it would be actual costs plus fixed fee) as suggested in the language of the RFP regardless of whether actual costs exceed estimates?

ANSWER 9

The total CPFF that has been obligated at contract award cannot be exceeded without approval, in writing, from the Contracting Officer. Actual costs, however, that are billed against the current obligated amount will be reimbursed up to the obligated amount as long as they are reasonable, allocable, and allowable in accordance with the Federal Acquisition Regulations (FAR). Once the contractor reaches 75% of the obligated amount, the Contracting Officer must be notified, in writing, in accordance with the Limitation of Cost clause (FAR 52.232-20). At that time, BARDA will determine whether or not additional funds will be obligated to fund the anticipated cost overrun under the contract. A determination to fund the cost overrun as identified in the revised estimate submitted by the Contractor does not affect the fixed fee (which remains unchanged in a cost overrun situation). Contractors who exceed the total CPFF on the contract without notification, in writing, from the Contracting Officer do so at their own risk.

QUESTION 10

Question #27 in the Q&A published 14Aug addressed the requirement for a long-term commitment to maintain a facility and the need to strike an appropriate balance between the Government's goals and the manufacturers business needs. We would like to request additional clarity on this issue.

Original Question #27: The requirement to maintain a facility of this complexity and size in an unpredictable market environment over such an extended period of time, as appears to be proposed in the draft RFP, creates a number of serious issues for any company. For example, if the technology is superseded or becomes obsolete, or if market conditions deteriorate in the seasonal influenza vaccine market such that it is uneconomical to continue production at the site, then the economics of such a long-term commitment could likely become untenable. As outlined in the questions and requests for clarification below, the exact obligations under the RFP are not entirely clear and we are interested in learning more. We hope that the final RFP when released will strike an appropriate balance between the Government's goals and manufacturers' business needs.

HHS Response to Question #27 (14Aug): Noted

Follow-up Question: The RFP requires that in exchange for partial funding of costs going forward, manufacturers take on significant responsibilities for up to 20 years, including yearly production of a pre-pandemic lot, maintenance of the ability at any time to be able to produce 150m doses within 6 months of the declaration of a pandemic and the production of other products at the facility in the event of a public health emergency.

It is highly likely that due to changes in technology and market conditions in the next 20 years, a financially responsible contractor would ultimately be obligated to use the US based facility for the manufacture of other products. As a result, the cost associated to change over from other products to mammalian, cell-based influenza vaccine and back again in an effort to produce the required 1 lot per year could result in a high cost per dose of annual pre-pandemic vaccine. Since the RFP indicates that the USG will not cover any production costs required to ramp up for the 1 lot per year (retrain operators, restart idle equipment, increase production efficiency, etc), this further compounds the problem.

As the long term requirements of the contract will put the contractor in an unfavorable business position which, among many other things will heavily impact the cost of the 1 lot per year options, would the Government consider amending the RFP in some way to lessen the burden on potential contractors? Alternatively will HHS consider allowing the contractors to negotiate in good faith new terms or to terminate the option period if circumstances in the influenza market deteriorate due to technology changes or if other non-viable market conditions prevail?

ANSWER 10
As stated in the RFP, it is the commitment of the offeror to maintain a facility in a manner that will allow for the production of pandemic influenza vaccine throughout the duration of this contract.

The contractor has the opportunity to propose contract modifications that support influenza vaccine technology advancements.

Please note that this contract does not support the advance development of an influenza vaccine.

QUESTION 11
Please clarify the responses to questions #53 and #56 published in the 14Aug Q&A (both shown below). The response to question #56 implies the facility may be used for other products as long as the facility remains in a state of readiness commensurate with the terms of the contract. However, the response to question #53 states that this solicitation does not support the design, construction and/or licensure of a multi-purpose facility. Please elaborate on these two responses.

Original Question #53: Based on the need to potentially also produce other emerging viruses, the contractor would assume that the plant should be set up as a multi-purpose facility. Can HHS please confirm?

HHS Response to Question #53 (14Aug): No, this solicitation does not support the design, construction and/or licensure of a multi-purpose facility.

Original Question #56: When the proposed facility is not being used for the production of cell-based pandemic influenza vaccine, warm based production in a non-pandemic

year, or an emerging infectious agent, will the awardee be allowed to produce another vaccine from the facility and/or influenza vaccine for the US or other markets?

HHS Response to Question #56 (14Aug): The facility, fully licensed for the manufacture of an influenza vaccine candidate, must remain in a state of readiness commensurate with the terms of the contract.

ANSWER 11
The purpose of this RFP is to support eligible contractors in the design, construction and licensure of a domestic facility to manufacture seasonal influenza vaccines. In order to remain in a state of readiness commensurate with the terms of the contract, the contractor must not compromise their ability to manufacture licensed seasonal influenza in the facility.

However, if the facility is utilized to manufacture other biologics, and the contractor is able to maintain their license to manufacture seasonal influenza, then the US Government would not object.

QUESTION 12
Responses to prior questions have indicated that the RFP does not support the design and construction of a multipurpose facility, but also that contractors may use the facility for other purposes during the contract term so long as all contractual obligations for both production and production capacity (including maintenance of licensure) under the contract are met. May contractors utilize equipment purchased under the RFP in conjunction with non-contract related activities at the facility so long as such activities do not interfere with contract performance?

ANSWER 12
Title and use rights in and to any equipment purchased under the RFP will be subject to the provisions of Part II, Section I.2 of the RFP, and the provisions of FAR Part 45, including but not limited to FAR 45.301(f).

QUESTION 13
Past Performance Questionnaire is included as Attachment 13. Please provide further instruction as to number of questionnaires to submit.

ANSWER 13
The solicitation instructs the offeror to submit information concerning their last 3 contracts completed during the last three years or information for the last three contracts currently in process. It does not require that the offeror submit the questionnaire as a part of their proposal or forward the questionnaire to their past performance references. Please ensure that you furnish accurate, complete contact information for references specified in your proposal to expedite the past performance evaluation.

QUESTION 14
Please clarify the definition of the term "Vaccine Candidate" used throughout the RFP. Is the term in reference to a pre-pandemic vaccine, seasonal vaccine or both?

ANSWER 14
Yes, the term 'Vaccine Candidate' refers to an offeror's seasonal and/or pre-pandemic influenza vaccine.